

# SYNTAX Trial 12-Month Outcomes

OBJECTIVE:	Study the roles of CABG and PCI using the TAXUS® Express® Stent in the contemporary management of left main* and/or three-vessel disease** patients
STENT:	TAXUS Express Stent
PURPOSE:	Safety and efficacy
DESIGN:	Prospective, randomized, consecutive all-comer patient enrollment, with limited exclusions: previous interventions, acute MI with CPK>2x, concomitant cardiac surgery
LESION:	<i>De novo</i> lesions in left main disease (isolated, +1, +2, +3 vessels) and/or three vessel disease (revascularization of all three vascular territories)
CONTROL:	Coronary artery bypass graft (CABG)
PRIMARY ENDPOINT:	Non-inferiority 12-month major cardiovascular or cerebrovascular event rate (MACCE†)
LOCATION & SITES:	62 E.U. sites and 23 U.S. sites
PATIENTS:	1,800 randomized patients
PRESENTERS:	Patrick W. Serruys MD, PhD and Friedrich W. Mohr MD, PhD

Patient Characteristics	TAXUS® Express® Stent (N=903)	CABG (N=897)	p-Value
Age, mean ± SD (years)	65.2 ± 9.7	65.0 ± 9.8	0.55
Male	76.4%	78.9%	0.20
BMI, mean ± SD	28.1 ± 4.8	27.9 ± 4.5	0.37
Diabetes	28.2%	28.5%	0.89
Hypercholesterolemia	78.7%	77.2%	0.44
Hypertension	74.0%	77.0%	0.14
Current Smoker	18.5%	22.0%	0.06
Prior MI	31.9%	33.8%	0.39
Unstable Angina	28.9%	28.0%	0.67
Additive EuroSCORE, mean ± SD	3.8 ± 2.6	3.8 ± 2.7	0.78
Total Parsonnet Score, mean ± SD	8.5 ± 7.0	8.4 ± 6.8	0.76
Total SYNTAX Score	28.4 ± 11.5	29.1 ± 11.4	0.19
Diffuse Disease or Small Vessels	11.3%	10.7%	0.69
No. Lesions, mean ± SD	4.3 ± 1.8	4.4 ± 1.8	0.44
3-Vessel Disease only	65.4%	66.3%	0.70
Left Main, any	34.6%	33.7%	0.70
Left Main only	3.8%	3.1%	0.46
Left Main + 1 Vessel	5.4%	5.1%	0.78
Left Main + 2 Vessels	11.5%	12.0%	0.72
Left Main + 3 Vessels	13.9%	13.5%	0.78
Total Occlusion	24.2%	22.2%	0.33
Bifurcation	72.4%	73.3%	0.67
Trifurcation	10.7%	10.6%	0.92

Patient Characteristics PCI Cohort	TAXUS Express Stent (N=903)
Staged Procedure	14.1%
Vessels Treated	
LAD	36.3%
Circumflex	32.5%
RCA	29.2%
Left Main	11.2%
Bi/Trifurcation	64.4%
Lesions Treated/Patient, mean ± SD	3.6 ± 1.6
No. Stents Implanted, mean ± SD	4.6 ± 2.3
Total Length Implanted, mm ± SD	86.1 ± 47.9
Range (mm)	8 - 324
Long Stenting (>100 mm)	33.2%

Data presented by Patrick W. Serruys MD, PhD and Friedrich W. Mohr MD, PhD, ESC 2008

† MACCE is defined as: all cause death, cerebrovascular accident (CVA/stroke), documented myocardial infarction (ARC definition Circ 2007; 115:2344-2351), any repeat revascularization (PCI and/or CABG)

\* Isolated or in conjunction with 1, 2, 3-vessel disease and \*\* revascularization for all 3 vascular territories

The safety and effectiveness of the TAXUS® Express® Stent have not been established in patients with diabetes, lesions located in an unprotected left main, multi-vessel disease, lesions requiring more than one stent or multiple overlapping stents, unresolved vessel thrombus at the lesion site, lesions located at a bifurcation, coronary artery reference vessel diameters <2.5mm or >3.75mm, lesions longer than 28mm, lesions located at a bifurcation, tortuous vessels (>60 degrees) in the region of the obstruction or proximal to the lesion, or in patients with moderate or severe calcification in the lesion.

Patient Characteristics CABG Cohort	CABG (N=897)
Off-pump Surgery	15.0%
Graft Revascularization	
Complete Arterial Revascularization	18.9%
At Least one Arterial Graft	97.3%
Double LIMA/RIMA	27.6%
LIMA + Venous	78.1%
Arterial Graft to LAD	95.6%
Radial Artery	14.1%
Venous Graft only	2.6%
Grafts per Patient, mean ± SD	2.8 ± 0.7
Distal Anastomosis per Patient, mean ± SD	3.2 ± 0.9

Procedural Characteristics	TAXUS® Express® Stent (N=903)	CABG (N=897)	p-Value
Time to Procedure - Days <sup>†</sup>	6.9 ± 13.0	17.4 ± 28.0	<0.001
Procedural Duration – Hours <sup>††</sup> , mean ± SD	1.7 ± 0.9	3.4 ± 1.1	<0.001
Post-procedural Hospital Stay – Days, mean ± SD	6.8 ± 7.7	14.0 ± 10.6	<0.001
Revascularization			
Complete <sup>***</sup>	56.7%	63.2%	0.005
Incomplete	43.3%	36.8%	0.005

12-month Clinical Event Rates	TAXUS Express Stent (N=903)	CABG (N=897)	p-Value
MACCE ( <i>failed to meet the non-inferiority primary endpoint</i> )	17.8%	12.1%	0.0015
Revascularization	13.7%	5.9%	<0.0001
All Death	4.3%	3.5%	0.37
CVA (Stroke)	0.6%	2.2%	0.003
MI	4.8%	3.2%	0.11
Death/MI/CVA	7.6%	7.7%	0.98

ITT population, Kaplan-Meier Rates, Fischer Exact Test

12-month Subgroup Analysis	TAXUS Express Stent MACCE Rate	CABG MACCE Rate	p-Value
All Left Main (n=705)	15.8%	13.7%	Not Reported
Left Main Isolated (n=91)	7.1%	8.5%	Not Reported
Left Main + 1 Vessel Disease (n=138)	7.5%	13.2%	Not Reported
Left Main + 2 Vessel Disease (n=218)	19.8%	14.4%	Not Reported
Left Main + 3 Vessel Disease (n=258)	19.3%	15.4%	Not Reported
3-Vessel Disease (w/o Left Main) (n=1,095)	19.2%	11.5%	Not Reported



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<sup>†</sup>Allocation to procedure

<sup>††</sup>For PCI patients, includes time for staged procedure

<sup>\*\*\*</sup>Per protocol: 'Complete revascularization is defined as the treatment of any lesion with more than 50% diameter stenosis in vessels ≥ 1.5 mm diameter as estimated on the diagnostic angiogram during the local Heart Team conference'. Completeness of revascularization was assessed post procedure by the operator (Surgeon or Interventional Cardiologist)

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